5.0 510(k) SUMMARY

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This 510(k) Summary for the BNX Fine Needle Aspiration System is being submitted in accordance with 21 CFR 807.92.

Submitter's Name and Address:	Beacon Endoscopic Corp. 2000 Commonwealth Ave. Suite 110 Auburndale, MA 02466-2008
Contact Person:	Annette Fagnant, Regulatory Affairs Consultant, MedDRA Assistance Inc. 53 Kennedy Road Foster, RI 02825 Phone: 401-392-0287 Fax: 401-397-6531
Date:	September 23, 2013
Name of Medical Device:	Device Regulation: 21 CFR 876.1075, Class II Product Code: FCG Common/Usual Name: Kit, Needle, Biopsy (FCG) Proprietary Name: BNX Fine Needle Aspiration System Classification Panel: Gastroenterology-Urology Devices Panel
Predicate Devices:	The subject device is substantially equivalent to the: • BNX Fine Needle Aspiration System (reference K103668, cleared December 30, 2010). The sharps safety protection mechanism is similar in design and use as that of the Personna Plus Safety Scalpel System (OMI Manufacturing Pty, Ltd, K032242, cleared September 23, 2003)
Device Description:	The BNX Fine Needle Aspiration (FNA) System is a sterile, single patient use endoscopic ultrasound aspiration needle. The device consists of the BNX Aspiration Delivery System and BNX Aspiration Needle which are assembled before insertion through the accessory channel of an ultrasound endoscope. The needle is used to acquire aspiration samples from lesions targeted using an ultrasound endoscope. An aspiration sample is obtained by penetrating the lesions with the needle while applying suction. The device is offered with needle sizes of 19, 22 and 25 gauge. The BNX FNA System has an integrated needle protection shield that automatically engages over the distal end of the needle during removal to cover the needle sharp. In this manner, the needle tip is covered to help protect against inadvertent needle sticks.

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Indication For Use:

The BNX FNA System is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle stick injury.

Technological Characteristics:

The proposed BNX FNA System has similar intended use and identical technological characteristics compared with the predicate BNX FNA System cleared in K103668. There have been no changes made to the design of the BNX FNA System to allow for the expanded labeling claim.

The referenced BNX FNA device incorporates a long stiff metallic needle with stylet housed in a sheath with handle assembly. The handle is screwed onto the luer-lock connection of the endoscope. The needle is manipulated by a handle piston which is locked and unlocked by means of a screw to avoid advancement of the needle during introduction and withdrawal of the biopsy assembly. The tips of the Aspiration Needles are etched for enhanced ultrasonic needle visualization. Tissue samples are acquired into the lumen of the needle via applied suction using a standard hypodermic syringe. The BNX FNA System is modular in design, i.e., the sheath and handle assembly are incorporated in a Delivery System as a separate component from the Aspiration Needle/stylet assembly. The modular design facilitates exchange of any size aspiration needle as the needle can be removed from the scope without requiring that the handle be disconnected. Additionally, the BNX FNA System has an integrated needle protection shield as a sharps injury protection feature that automatically engages over the distal end of the needle during removal to cover the needle sharp. In this manner, the needle tip is covered to help protect against inadvertent needle sticks. If a second sample acquisition cycle is required, the needle protector shield is captured within the handle housing to be actuated during the next needle removal cycle.

Performance Data:

Bench and simulated use testing were performed demonstrating that the subject device is substantially equivalent to the predicate devices for the proposed intended use. As per CDRH's Guidance for Industry and FDA: Medical Devices with Sharps Injury Prevention Features, simulated use studies were conducted on the subject device evaluating greater than 500 cycles of product use with zero failures for the sharps injury prevention feature. Results of this evaluation met FDA's minimum standard for a "97.5% confidence that the true failure rate was no higher than 0.7% and 99.5% confidence that it is no higher than 1.1% " as per the FDA Guidance and documented that the BNX FNA System's passive sharps safety prevention mechanism did not impede or adversely affect the intended clinical performance of the device and provided protection against unintended sharps injury through disposal.

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Conclusion: Beacon Endoscopic Corp. has demonstrated that the proposed BNX FNA System is substantially equivalent to the predicate BNX FNA System and has demonstrated that the passive needle protection sheath provides sharps safety protection supporting expansion of the device's indication to include that the needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle stick injury.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2013

Beacon Endoscopic Corporation
% Annette M. Fagnant
Regulatory Affairs Consultant
MedDRA Assistance, Inc.
53 Kennedy Road
Foster, RI 02825

Re: K133008
Trade/Device Name: BNX Fine Needle Aspiration System
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: September 23, 2013
Received: September 25, 2013

Dear Annette M. Fagnant,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K133008

4.0 Indication for Use Statement

510(k) Number (if known):

Device Name: BNX Fine Needle Aspiration System

Indications for Use:

The BNX FNA System is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope. *The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle stick injury.*

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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